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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/237,969	01/27/1999	DAVID ALEXANDER	IMMR-023/01US	6872

22903 7590 05/15/2003

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EXAMINER

SOTOMAYOR, JOHN

ART UNIT	PAPER NUMBER
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3714

DATE MAILED: 05/15/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/237,969

Applicant(s)

ALEXANDER ET AL.

Examiner

John L Sotomayor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-173 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 85-90, 92-95, 97, 101-106, 127, 128, 131, 132, 140, 143-148 and 163-165 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8, 15, 16. 6) ☐ Other:

Continuation of Disposition of Claims: Claims withdrawn from consideration are 91,96,98-100,107-126,129,130,133-139,141,142,149-162 and 166-173.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 14 is acknowledged. In response to applicant's amendment filed 2/24/2003, claims 91,96,98-100,107-113,114-126,129-130,133-139,141-142,149-162, and 166-173 are cancelled which are directed to the non-elected inventions Group I, Species 2, Group II and Group III and claims 85-90, 92-95, 97, 101-106, 127,128,131,132,140,143-148 and 163-165 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 85-88,90,92-95,97,101-105,128,131-132,140,143-147,164 and 165 are rejected under 35 U.S.C. 102(e) as being anticipated by Bailey (US 5,800,179).

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5. Regarding claim 85, Bailey discloses an apparatus with a peripheral selectively manipulable by the user and corresponding to a medical instrument, and orifice for receiving said peripheral, a capture mechanism for engaging said peripheral to enable said interface apparatus to measure manipulation of said peripheral, and a sensing assembly to measure and transmit performance information from simulated medical procedure performed with the medical instrument (Col 3, lines 45-67, Col 4, lines 9-14 and figure 1).
6. Regarding claim 86, Bailey discloses an apparatus in which the medical instrument is an endoscope and the method used is an endoscopic procedure (Col 5, lines 15-16).
7. Regarding claim 87, Bailey discloses an apparatus with a simultaneous plurality of capture mechanisms and sensing assemblies simulating a plurality of medical instruments in the instrument assembly (Col 5, lines 1-22).
8. Regarding claim 88, Bailey discloses an apparatus with a pivoting mechanism to pivot the orifice in the housing (Col 5, lines 35-50 and Fig. 2).
9. Regarding claim 90, Bailey discloses that at least one of the instruments includes a nested instrument assembly (Col 5, lines 1-22).
10. Regarding claim 92, Bailey discloses a method for simulating a medical procedure including inserting a peripheral into an orifice and manipulating the peripheral within the interface, measuring the manipulation of the peripheral via the sensing assembly, and transmitting the captured information from the interface to the simulation system (Col 3-5).
11. Regarding claim 93, Bailey discloses a method wherein the medical instrument includes an endoscope (Col 5, lines 15-16).

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12. Regarding claim 94, Bailey discloses a method in which a nested instrument assembly simulates a plurality of medical instruments in the instrument assembly enabling the interface to measure manipulation of the instrument, and transmit the collected information from the interface to the simulation system (Col 5).
13. Regarding claim 95, Bailey discloses a method in which the medical instrument may be pivoted to the desired orientation (Col 5, lines 23-37).
14. Regarding claim 97, Bailey discloses a method in which force feedback is applied in response to control signals from the simulation system (Col 3, lines 45-67).
15. Regarding claim 101, Bailey discloses an apparatus in which the medical instrument is an endoscope and the method used is an endoscopic procedure (Col 5, lines 15-16).
16. Regarding claims 102-104, Bailey discloses an apparatus in which the instrument simulated is an endoscope with a working channel containing a measurement sensor to simulate performance of a medical procedure (claim 102), in which the peripheral further includes a working channel force feedback unit to apply force feedback (claim 103), and in which the peripheral includes a navigation tube for insertion into the interface apparatus, a tube control peripheral at the distal end of the navigation tube, and a sensor (Col 3-5, fig. 1&2).
17. Regarding claim 105, Bailey discloses a method in which a nested instrument assembly simulates a plurality of medical instruments in the instrument assembly each selectively manipulable by the user, a plurality of capture mechanisms to engage the nested instruments, and a sensing assembly to enable the simulation system to simulate performance of a medical procedure with the nested instrument assembly (Col 5 & 6).

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18. Regarding claim 128, Bailey discloses an interface apparatus comprising a peripheral selectively manipulable and corresponding to a medical instrument, a sensing assembly to measure and transmit information during the medical procedure simulation, a mock anatomical site having an orifice for receiving the medical instrument, and a pivoting mechanism to selectively pivot the mock anatomical site (Col 4 and 5, fig. 2).

19. Regarding claim 131, Bailey discloses a method in which a nested instrument assembly simulates a plurality of medical instruments in the instrument assembly each selectively manipulable by the user, a plurality of capture mechanisms to engage the nested instruments, and a sensing assembly to enable the simulation system to simulate performance of a medical procedure with the nested instrument assembly in which the sensing assembly contains rotation and translation sensors and motion capability arranged successively (claim 131) (Col 5 & 6, fig. 4) or in parallel (claim 132) (fig. 2).

20. Regarding claim 140, Bailey discloses a method for applying force feedback to a peripheral in response to control signals from the simulation system (Col 3, lines 45-67).

21. Regarding claim 143, Bailey discloses an apparatus in which the medical instrument is an endoscope and the method used is an endoscopic procedure (Col 5, lines 15-16).

22. Regarding claims 144 and 145, Bailey discloses an apparatus in which the instrument simulated is an endoscope with a working channel containing a measurement sensor to simulate performance of a medical procedure, in which the peripheral further includes measuring the manipulation of the working channel peripheral via the sensor and transmitting information associated with the working channel peripheral manipulation (Col 3-5, fig. 1&2).

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23. Regarding claim 146, Bailey discloses an apparatus in which the instrument simulated is an endoscope with a working channel containing a measurement sensor for measuring manipulation of tube position control, and transmitting information associated with tube position control during performance of the medical procedure (Col 5-6, fig. 5 & 6).

24. Regarding claim 147, Bailey discloses an apparatus in which the peripheral simulated is a nested instrument in which nested instruments are engaged with a working channel containing a measurement sensor for measuring manipulation of tube position control, and transmitting information associated with tube position control during performance of the medical procedure (Col 5-6, fig. 5, 6).

25. Regarding claim 164, Bailey discloses an interface operatively coupling a peripheral to a sensing assembly, selectively pivoting the mock anatomical site to a particular orientation, measuring manipulation of the peripheral via the sensing assembly, and transmitting information associated with the measured manipulation of the corresponding medical instrument in accordance with the peripheral manipulation (Col 4-6, fig. 1 & 2).

26. Regarding claim 165, Bailey discloses an interface operatively coupling a peripheral to a sensing assembly, simulating forces and movement of the orifice during performance of the medical procedure and positioning the guide tube within the interface, measuring manipulation of the peripheral via the sensing assembly, and transmitting information associated with the measured manipulation of the corresponding medical instrument in accordance with the peripheral manipulation (Col 4-6, fig. 1, 5, 6).

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Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. Claims 89,106,127,148,and 163 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey in view of Jacobus et al (US 5,769,640) in further view of Gillio (US 5,800,178).

30. Regarding claims 89,106,127,148, and 163, Bailey does not specifically disclose an interface and simulation device containing a plurality of peripherals in the form of medical instruments for use in the simulation of a medical procedure. However, Gillio teaches that a single peripheral instrument may be interchanged within a medical simulation assembly device for simulating a plurality of medical procedures (Col 5) and Jacobus et al teaches that multiple devices simulating a plurality of medical instruments are used within a medical simulation interface to simulate a plurality of devices in use simultaneously (Col 7). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a system

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and method for the simulation of a medical procedure comprising a plurality of devices for use in the simulation of a medical procedure. Combining the system and method disclosed by Bailey with the teachings of Gillio and Jacobus et al produces a flexible medical simulation system with broader capability to teach medical procedures to students.

Conclusion

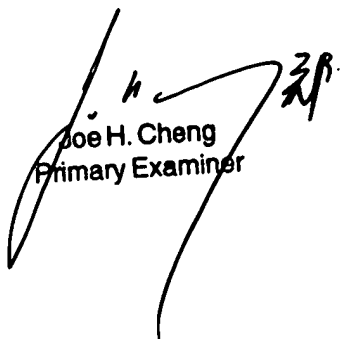
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gillio (US 5,800,177) for a discussion of plurality interface devices for medical procedures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John L Sotomayor whose telephone number is 703-305-4558. The examiner can normally be reached on 6:30-4:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Hughes can be reached on 703-308-1806. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-8361 for regular communications and 703-746-8361 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-4558.

jls
May 2, 2003


Joe H. Cheng
Primary Examiner